TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Thiazolidinediones (TZDs)

Effective: March 10, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products
- ☐ Tufts Health Plan Commercial products – large group plans
- ☐ Tufts Health Plan Commercial products – small group and individual plans
- ☐ Tufts Health Freedom Plan products – large group plans
- ☐ Tufts Health Freedom Plan products – small group plans
- CareLink[SM] – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products
- ☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
- ☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
- ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

ActoPlus Met XR (pioglitazone/metformin extended release tablet) is a thiazolidinedione and biguanide combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both pioglitazone and metformin is appropriate.

Avandia (rosiglitazone) is a thiazolidinedione indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Neither Avandia nor ActoPlus Met XR is indicated for the treatment of type 1 diabetes or diabetic ketoacidosis.

Thiazolidinediones (TZDs) have a Black Box Warning regarding heart failure; TZDs have been associated with causing or exacerbating congestive heart failure. They are not recommended in patients with symptomatic heart failure. ActoPlus Met XR also has a Black Box Warning for lactic acidosis. If lactic acidosis is suspected, ActoPlus Met XR should be discontinued.

The American Diabetes Association (ADA) guidelines recommend metformin, if not contraindicated and if tolerated, as first line for the treatment of type 2 diabetes. If noninsulin monotherapy at the maximum tolerated dose does not achieve or maintain the A1C target after three months of treatment, then add-on agents to be considered include a sulfonylurea, a thiazolidinedione (TZD), a dipeptidyl peptidase-4 (DPP-4) inhibitor, a sodium-glucose co-transporter 2 (SGLT-2) inhibitor, a GLP-1 agonist, or basal insulin should be added to the patient's treatment regimen. The choice of add-on treatments is based upon patient- and disease-specific factors.

Tufts Health RITogether prefers generic pioglitazone, pioglitazone-metformin, and pioglitazone-glimepiride tablets.

COVERAGE GUIDELINES

The plan may authorize coverage of a thiazolidinedione (TZD) for Members when **all** of the following criteria are met:

1. Member has had an inadequate response, intolerance, or contraindication to metformin at the highest tolerated dose

AND

2. Member had an inadequate response to pioglitazone and at least one additional generic oral antidiabetic agent. Examples include sulfonylureas (glimepiride, glipizide, glyburide), thiazolidinedione (pioglitazone), meglitinide analgoues (nateglinide, replaglinide), and DPP-4 inhibitor (alogliptin).

LIMITATIONS

None

CODES

None

REFERENCES

1. ActoPlus Met (pioglitazone and metformin extended-release) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; December 2017.
2. Actos (pioglitazone) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; December 2017.
3. Avandia (rosiglitazone) [prescribing information]. GlaxoSmithKline: Research Triangle Park, NC; February 2019.
4. American Diabetes Association. Standards of medical care in diabetes – 2020. *Diabetes Care*. 2020;43(Suppl. 1):S1-S212.

APPROVAL HISTORY

May 9, 2017: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. October 16, 2018: Administrative update to template.
2. April 9, 2019: No changes.
3. March 10, 2020: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.